

REMARKS

This is a full and timely response to the outstanding FINAL Office Action mailed February 21, 2007. The Examiner is thanked for the thorough examination of the present application. Upon entry of the amendments in this response, claims 1-14, 20, and 21 are pending in the present application.

Claims 2-8 are rejected under 35 U.S.C. §112, 2nd paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-8, 10-14, 20-21 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by *Brunkens* (European Patent No. 0 615 726 A1). Claims 1 and 11 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by *Matsutani, et al.* (U.S. Pat. No. 4,935,029, hereinafter *Matsutani*). Finally, claim 9 is rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Brunkens* in view of *Anis* (U.S. Pat. No. 5,352,233).

Applicant respectfully requests consideration of the following amendments and remarks contained herein. Reconsideration and allowance of the application and presently pending claims are respectfully requested.

I. Response to Claim Rejections Under 35 U.S.C. § 112

Claim 1 has been rejected under 35 U.S.C. § 112, 2nd paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. In response to the rejection, Applicant has amended claims 2 and 6 to overcome the §112 rejection. Claim 4 has been canceled. Applicant respectfully requests that the rejection under 35 U.S.C. §112 rejection be withdrawn.

II. Response to Claim Rejections Under 35 U.S.C. § 102

Claims 1-8, 10-14, 20-21 have been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by *Brunkens*. Claims 1 and 11 have also been rejected under 35 U.S.C. §102(b) as allegedly being anticipated by *Matsutani*. For at least the reasons set forth below, Applicant traverses these rejections.

Independent Claim 1 is Patentable Over Brunkens

Claim 1, as amended, recites (emphasis added):

1. A suture needle comprising:
a shaft and a puncture tip at one end of a curve of the shaft,
wherein the shaft is comprised of a front surface and a rear surface
that extend side-by-side along at least a portion of a length of the shaft
and wherein the shaft is marked at least partially with a visual indicator,
and

**wherein the rear surface is distal the puncture tip, and wherein
at least one of the rear surface and the front surface includes
the visual indicator.**

In the "Response to Arguments" section, the Office Action states the following:

All suture needles have a front and rear surface that extend side-by-side along the length of the shaft, including the needle taught by *Brunkens* '726. Applicant does not claim a visual indicator differentiating between the front and rear portions that extend side-by-side. Therefore, *Brunkens* '726 meets the limitations of the claims.

As indicated above, Applicant has amended claim 1 only to clarify that the visual indicator lies either on the front surface or the rear surface (which extend side-by-side along at least a portion of a length of the shaft) to differentiate between the two surfaces. Claim 1 now recites: "wherein the rear surface is distal the puncture tip, and wherein at least one of the rear surface and the front surface includes the visual indicator." The *Brunkens* reference fails to teach this feature. The *Brunkens* reference, instead, teaches the following (emphasis added):

[T]he surface of the puncture tip and of the zone of the needle adjoining same consists of bare or untreated metal, while the surface of the remaining section of the needle, which can account for up to ca. 50% of the needle length, is matt-finished or coloured.

Page 3, lines 29-31. Unlike the *Brunkens* reference, the present invention is comprised of a distinct front and rear surface that extends side-by-side along at least a portion of the length of the shaft and where a visual indicator differentiates between the two surfaces. *Brunkens* instead teaches of different zones or sections and fails to teach a suture needle comprised of two surfaces that extend side-by-side along at least a portion of the length of the shaft. The first zone/section consists of bare or untreated metal, while the surface of the remaining section of the needle is matt-finished or coloured. This is clearly seen in FIG.1 of the *Brunkens* reference. (See *Brunkens*, zone (8) and section (10) in FIG. 1, reproduced below.)

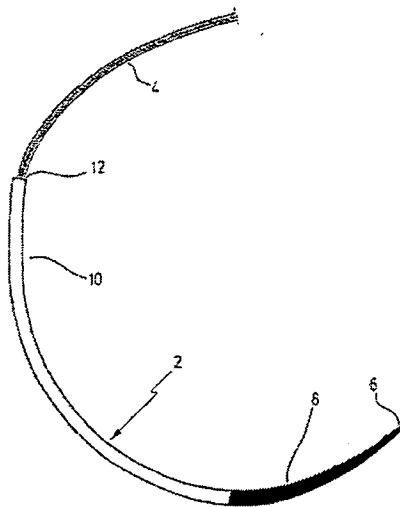


FIG. 1

Applicant submits that *Brunk*en fails to disclose, teach, or suggest the features emphasized in claim 1. Accordingly, Applicant respectfully submits that independent claim 1 patently defines over *Brunk*en for at least the reason that *Brunk*en fails to disclose, teach, or suggest the features emphasized above in claim 1.

Independent Claim 1 is Patentable Over Matsutani

Regarding the *Matsutani* reference, the Office alleges on page 6 that the *Matsutani* reference discloses a visual indicator on a needle that differentiates with a color between the inner and outer portions of the needle along its shaft. In alleging that the *Matsutani* reference teaches the features of claim 1, the Office Action refers to FIGS. 12-16 and specifically to “band 4” in FIG. 16. The Office Action further alleges that “*it would be obvious to extend these visual indicators along the entire shaft in order to aid a surgeon in recognizing the orientation of the needle at the distal tip (columns 10-11.)*” However, Applicant respectfully disagrees and submits that it would not have been obvious to extend the visual indicator (*i.e.*, “band 4” as referred to by the Office Action) along the entire shaft of the needle.

Matsutani fails to teach “the shaft is comprised of a front surface and a rear surface . . . wherein the rear surface is distal the puncture tip, and wherein at least one of the rear surface and the front surface includes the visual indicator,” as recited in claim 1. To clarify, the phrase “wherein the rear surface is distal the surface tip” refers to the fact that the rear surface is outside the curve of the shaft and not to the fact that the rear surface lies along a point away from the point of the needle (*e.g.*, as with the welded portion (4) with respect to the point of the needle in the *Matsutani*

reference).

Furthermore, the welded portion (4) cited by the Office Action is not the same as the shaft recited in claim 1. The welded portion (4) of *Matsutani* is a separate component than the needle member (1). The needle member (1) and the pipe member (2) are formed of austenitic stainless steel and are welded together, resulting in the welded portion (4). It would not "have been obvious to extend the visual indicator (i.e., the welded portion (4)) along the entire shaft," as alleged by the Office Action. The *Matsutani* reference clearly makes the distinction between the welded portion (4) and the needle member (1). Indeed, the abstract of the *Matsutani* reference states (emphasis added):

In a surgical needle, marks of welding are left as they are on a welded portion between needle and pipe members so that the welded portion has a surface distinguishable from peripheral surfaces of the respective needle and pipe members.

Applicant also submits that it would not be obvious to extend the welded portion down the length of the shaft because the purpose of the welding portion (4) is not to visibly distinguish between the front surface and the rear surface of the needle. Rather, the *Matsutani* reference teaches the following (emphasis added):

The ring-like welded portion 4 serves as a mark when, for example, the pipe member 2 is staked, so that it can be ensured that a part (designated by the character 2a in FIG. 5) of the pipe member 2 spaced a predetermined distance from the welded portion 4 is staked. This makes it possible to prevent occurrence of cracks or the like in the pipe member 2 due to staking of the welded portion 4 or a part very close thereto. Moreover, the ring-like welded portion 4 serves also as a mark by which when a doctor clamps the surgical needle with a chuck jig at a surgical operation, he can clamp the surgical needle while keeping away from the pipe member 2 which is low in strength.

Col. 7, lines 17-30.

In response to the allegation that it would have been obvious to extend the visual indicator (*i.e.*, welded portion (4)) down the entire length of the shaft, the *Matsutani* reference specifically teaches how the welding is carried out with respect to only predetermined angular extents along the abutting line 3 (in FIG. 7) (emphasis added):

In each of embodiments shown respectively in FIGS. 12 through 15, welding is carried out with respect **only to predetermined angular extents along the abutting line 3**, in order to enable a surgical needle to have an especial function.

Col. 10, lines 11-15. Therefore, if anything, *Matsutani* appears to teach away from extending the welding portion down the entire length of the needle. The U.S. Court of Appeals for the Federal Circuit has stated that “[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.” *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)) (emphasis added).

For at least the reasons described above, *Matsutani* fails to teach of the visual indicator such that “the rear surface is distal the puncture tip, and wherein at least one of the rear surface and the front surface includes the visual indicator” as recited in claim 1. Even assuming, *arguendo*, that the welded portion of the *Matsutani* reference is equivalent to the visual indicator in claim 1 (“wherein the shaft is marked at least partially with a visual indicator along either the front surface or the rear surface to differentiate between the two surfaces”), it would not have been obvious to extend the welded portion taught by *Matsutani* along the entire shaft, as alleged by the Office

Action. Accordingly, Applicant respectfully submits that independent claim 1 patently defines over *Matsutani* for at least the reason that *Matsutani* fails to disclose, teach, or suggest the features emphasized above in claim 1.

Dependent Claims 2, 3, and 5-10 are Patentable

Applicant submits that dependent claims 2, 3 and 5-10 are allowable for at least the reason that these claims depend from an allowable independent claim. See, e.g., *In re Fine*, 837 F. 2d 1071 (Fed. Cir. 1988).

Independent Claim 11 is Patentable Over Brunkens

Claim 11 recites (emphasis added):

11. A suture needle comprising:
a puncture tip; and
a shaft extending from the puncture tip, the shaft including means for distinguishing between a front surface of the shaft and a rear surface of the shaft, **wherein the front surface and the rear surface extend side-by-side along at least a portion of the length of the shaft.**

In the “Response to Arguments” section, the Office Action fails to specifically address the arguments made by the Applicant in the prior response regarding claim 11. As clearly seen in FIG. 1 of the *Brunkens* reference, *Brunkens* fails to teach of “means for distinguishing between a front surface of the shaft and a rear surface of the shaft, wherein the front surface and the rear surface extend side-by-side along at least a portion of the length of the shaft.”

Applicant respectfully maintains that *Brunkens* instead teaches of different zones or sections and does not teach a suture needle comprised of two surfaces that extend the length of the shaft. The first zone/section consists of bare or untreated metal, while

the surface of the remaining section of the needle is matt-finished or coloured. This is clearly illustrated in FIG.1 of the *Brunkens* reference. See *Brunkens*, zone (8) and section (10) in FIG. 1, reproduced on p. 9, *supra*. Accordingly, Applicant respectfully submits that independent claim 1 patently defines over *Brunkens* for at least the reason that *Brunkens* fails to disclose, teach, or suggest the features emphasized above in claim 11.

Independent Claim 11 is Patentable Over Matsutani

Regarding the *Matsutani* reference, *Matsutani* fails to teach the feature, "a shaft extending from the puncture tip, the shaft including means for distinguishing between a front surface of the shaft and a rear surface of the shaft, wherein the front surface and the rear surface extend side-by-side along at least a portion of the length of the shaft." The molded portion (4) referred to by the Office Action is not actually part of the needle member itself. The welded portion, pipe member and needle member are all clearly distinguished within the text (See, e.g., abstract of *Matsutani* reference; "In a surgical needle, marks of welding are left as they are on a welded portion between needle and pipe members so that the welded portion has a surface distinguishable from peripheral surfaces of the respective needle and pipe members").

In response to the allegation that it would have been obvious to extend the visual indicator (i.e., welded portion (4)) down the entire length of the shaft, the *Matsutani* reference specifically teaches how the welding is carried out with respect to only predetermined angular extents along the abutting line 3. See *Matsutani*, FIG. 7. Accordingly, Applicant respectfully submits that independent claim 11 patently defines

over *Matsutani* for at least the reason that *Matsutani* fails to disclose, teach, or suggest the features emphasized above in claim 11.

Dependent Claims 12-14 are Patentable

Applicant submits that dependent claims 12-14 are allowable for at least the reason that these claims depend from an allowable independent claim. See, e.g., *In re Fine*, 837 F. 2d 1071 (Fed. Cir. 1988).

Independent Claim 20 is Patentable Over Brunkens

Claim 20, as amended, recites (emphasis added):

20. A method of making a suture needle, comprising the steps of:
providing a suture needle; and
marking at least a portion of the suture needle with a visual indicator, wherein the portion extends at least partially the length of the suture needle, wherein the step of marking a portion of the suture needle comprises marking a surface of a shaft of the needle chosen from a front surface and a rear surface, wherein the front surface is the surface inside a curve of a shaft of the suture needle.

Applicant has amended claim 20 and canceled claim 21. Applicant further submits that no new subject matter is added by the amendment. The amendment was only made to clarify that the front surface and the rear surface are defined such that the front surface is the surface inside the curve of the needle shaft. In rejecting claim 21 on page 4, the Office Action alleges that *Brunkens* discloses a front surface that is a different color than the rear surface of the needle. However, Applicant submit that the amendment made to claim 20 clarifies that the "front" and "rear" surfaces are defined differently than the surfaces disclosed in the *Brunkens* reference. *Brunkens* discloses surfaces or zones that are defined according to sections or zones that lie along the

length of the needle (e.g., "ca. 50% of the needle length"). The front and rear surfaces that the Office Action refers to in the *Brunkens* reference is different than the front and rear surfaces defined by claim 20, as reflected by the language emphasized above. Accordingly, Applicant respectfully submits that independent claim 20 patently defines over *Brunkens* for at least the reason that *Brunkens* fails to disclose, teach, or suggest the features emphasized above in claim 20.

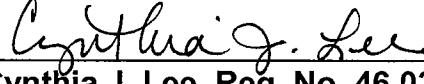
CONCLUSION

In light of the foregoing amendments and for at least the reasons set forth above, Applicant respectfully submits that all objections and/or rejections have been traversed, rendered moot, and/or accommodated, and that the now pending claims are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are hereby courteously requested.

Any other statements in the Office Action that are not explicitly addressed herein are not intended to be admitted. In addition, any and all findings of inherency are traversed as not having been shown to be necessarily present. Further, any and all findings of well-known art and official notice, or statements interpreted similarly, should not be considered well known for at least the specific and particular reason that the Office Action does not include specific factual findings predicated on sound technical and scientific reasoning to support such conclusions.

If, in the opinion of the Examiner, a telephone conference would expedite the examination of this matter, the Examiner is invited to call the undersigned attorney at (770) 933-9500.

Respectfully submitted,



Cynthia J. Lee, Reg. No. 46,033

**THOMAS, KAYDEN,
HORSTEMEYER & RISLEY, L.L.P.**
100 Galleria Parkway N.W.
Suite 1750
Atlanta, Georgia 30339
(770) 933-9500